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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,398	11/14/2003	James W. Lillard JR.	1013-015	6848

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
11/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTODC@andrewskurth.com

Office Action Summary	Application No.	Applicant(s)	
	10/712,398	LILLARD ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 21- 29* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23-25,28 and 29* is/are rejected.

7)☒ Claim(s) *26 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 19 and 21- 29 are pending.
Claims 21 and 22 have been withdrawn.
Claims 19 and 23- 29 are under currently under examination.

35 USC § 102(e) rejections maintained

The rejection of claims 19 , 23 and new claims 24, 25 28 and 29 under 35 U.S.C. 102(e) as being anticipated by Andrews et al (US Patent No. 6,936,248, issued Aug 30, 2005, filed March 10, 2000) are maintained.

The claims are drawn to a method of inhibiting malignant cell migration and metastasis in a host having a malignancy which is melanoma, by administering of an effective amount of a composition containing anti-CCL25 antibodies, wherein the antibody is humanized, wherein the pharmaceutical acceptable carrier is saline, wherein the antibody is administered intravenously or subcutaneously.

Andrews et al., disclose treating patients with melanoma with antibodies to TECK (CCL25). (column 29, lines 53-57; column 30, lines 31-45), wherein the antibody is humanized. (column 9, lines 38-46), wherein the antibody is administered intravenously or subcutaneously in saline and in a barrier device. (column 32, lines 22 to column 33, line 40).

Applicants state that Claim 19, as amended, is directed to a method of inhibiting malignant cell migration in a host having a malignancy which is melanoma by administration of a migration-inhibiting effective amount of a composition containing anti CCL25 antibodies in a pharmaceutically acceptable carrier. Applicant argue that, in contrast, Andrews generally mentions the inhibition of inflammatory processes by using an antibody that inhibits the binding of a ligand to GPR-9-6. Applicants further argue that Andrews does not teach or suggest treating a host with a migration-inhibiting effective amount of a composition containing anti-CCL25 antibodies in a pharmaceutically acceptable carrier. Applicants argue that Andrews does not mention the migration of melanoma cells at all. Applicants argue that Andrews mentions antagonism of the GPR-9-6 receptor as it pertains to inhibiting inflamatory processes, not the migration of melanoma as in the presently Claim 19. Applicants argue that Claim 19 is patentable over Andrews because Andrews does not teach every element of Claim 19.

Applicants arguments have been considered but are not persuasive. The active step of claim 19, the administration of a composition of an anti-CCL25 antibody to a host having melanoma is identical to that disclosed in Andrews et al. Applicants have not convincingly demonstrated that the composition of anti-CCL25 antibody in Andrews et al is distinct from that in claim 19. The fact that Andrews et al did not disclose that the administration of anti-CCL25 antibody inhibits the migration of melanoma cells is not determinative of novelty.

MPEP 2112 states

> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

MPEP 2112 further states

> There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)

Applicants have not demonstrated the composition of anti-CCL25 antibody in Andrews et al is distinct from the composition of anti-CCL25 antibody in claim 19. Both Andrews et al and the present claims disclose the administration of anti-CCL25 antibodies to a melanoma patient.

Summary

Claims 19, 23-25, 28 and 29 stand rejected.

Claims 26 and 27 stand objected to for being dependent on a rejected claim. Andrews et al does not disclose that the antibody is administered directly to the tumor tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/
Examiner, Art Unit 1642